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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

KIM CHANNING on behalf of herself as an heir at law of ELGA IDA HINDIN and as Executor of the Estate and/or Successor in Interest of ELGA IDA HINDIN; JENNIFER LYNN RICHARDS; JEFFREY PAUL HINDIN and GERALDINE G. HINDIN

Plaintiffs;

v.

JOHNSON & JOHNSON; ORTHO-MCNEIL PHARMACEUTICAL, INC.; JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, LLC

Defendants.

Civil Action No. CV 08 2913

JURY DEMAND

WRONGFUL DEATH COMPLAINT AND JURY DEMAND

Plaintiffs, by and through her attorneys of record, hereby files this Complaint and Demand for Jury Trial against Defendants Johnson & Johnson, Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil"), and Johnson & Johnson Pharmaceutical Research & Development, LLC ("Johnson & Johnson Pharmaceuticals") (collectively referred to as "Defendants"),

states on information and belief as follows:

INTRODUCTION

1. This case involves the fluoroquinolone antibiotic, levofloxacin.

2. Levofloxacin was designed, formulated, promoted, sold and distributed by Defendants in the United States as Levaquin® from 1997 though the present.

3. Levaquin was approved by the United States Food and Drug Administration ("FDA") for treatment of a variety of serious infections. However, Defendants market Levaquin as a first line therapy for common bronchitis and sinusitis infections, and for which many other, safer, antibiotics are available.

4. As compared to other fluoroquinolone antibiotic drugs, Levaquin causes a higher incidence of tendon injuries, including tendon rupture, especially in persons over 60 years of age and/or who are on corticosteroids therapy, none of which was adequately disclosed to Elga Ida Hindin and her healthcare providers.

5. Levqaquin – induced tendon injury involves the degradation of the tendon tissue, leading to severe and permanent injuries. Levaquin in some cases may also cause central nervous system effects, clostridium difficile associated diarrhea, peripheral neuropathies and acute renal failure.

6. Elga Ida Hindin took Levaquin which caused one or more of these effects which caused her to die on June 13, 2006.

7. This lawsuit asserts claims against Defendants for wrongful death as a result of negligence, strict product liability for manufacturing and/or design defects; strict product liability for failure to warn; breach of express and implied warranties for the design, manufacture, production, testing, study inspection, labeling, marketing, advertising, sales, promotion, and distribution of Levaquin.

JURISDICTION

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000), exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiffs and Defendants.

9. Venue in this Court is proper pursuant to 28 U.S.C. §1391 in that substantial part of the events or omissions giving rise to the claims asserted herein occurred in this District (Defendants researched, designed, licensed, manufactured, tested, marketed, distributed, and/or sold the prescription drug Levaquin within the judicial district), and Defendants are subject to personal jurisdiction in this district.

10. Plaintiff Kim Channing is a citizen and resident of the state of California and resides in the County of Sonocma.

11. Plaintiff Jennifer Richards is a citizen and resident of the state of California and resides in the County of Sonocma.

12. Plaintiff Jeffrey Paul Hindin is a citizen and resident of the state of California and resides in the County of Mairn.

13. Plaintiff Geraldine G. Hindin is a citizen and resident of the state of California and resides in the County of San Francisco.

14. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

15. Defendant Ortho-McNeil is a Delaware Corporation with its principal place of business in Raritan, New Jersey. Defendant Ortho-McNeil is a wholly owned subsidiary of Johnson & Johnson.

16. Defendant Johnson & Johnson Pharmaceutical Research & Development is a New Jersey corporation with its principal place of business in Raritan, New Jersey. Defendant Johnson & Johnson Pharmaceutical is a wholly owned subsidiary of Johnson & Johnson and was formerly known as R.W. Johnson Pharmaceutical Research Institute.

17. At all times relevant herein, Defendants tested, studied, researched designed, formulated, manufactured, inspected, labeled packaged, promoted, advertised, marketed, distributed, and sold the prescription drug Levaquin in interstate commerce and throughout the State of Texas. At all times relevant herein, Defendants were registered to do business in the State of Texas.

FACTS

18. Levaquin, Defendants' brand name for the antibiotic levofloxacin, is a broad spectrum synthetic antibacterial agent approved for use in the treatment of a variety of upper respiratory infections, urinary tract infections, prostatitis, and other bacterial infections. It was first introduced into the U.S. market in 1997.

19. Levaquin is a class of antibiotics known as fluoroquinolones. The original quinolone antibiotics were developed in the early 1960's and soon revealed themselves as highly effective against common gram-negative bacteria, but resistance developed rapidly. Twenty years later, in the early 1980's, fluorinated derivatives of the quinolones emerged, revealing a broader, more potent antibiotic, effective against many different types of infections. These so-called second generation fluoroquinolones included norfloxacin (Noroxin), ciprofloxacin (Cipro), ofloxacin (Floxin), and pefloxacin (never marked in the United States).

20. Although considered highly effective at killing certain bacteria, fluoroquinolones have long been associated with serious side effects. Indeed, many

fluoroquinolones have been removed from the market due to intolerable adverse events. For example, Omniflox (temaflocacin) was removed from the market in 1992 because of low blood sugar, kidney failure, and a certain fare form of anemia; Raxar and Zagam were removed because of QT-interval prolongation among other things; Trovan was removed from the market due to severe liver toxicity; and most recently, Tequin was removed from the market in 2006 amid reports of sever blood sugar reactions such as hyperglycemia and hypoglycemia.

21. In sum, though fluoroquinolones may share certain pharmacological properties, their safety profiles can differ immensely.

22. To understand the pharmacological properties of Levaquin, one need look no further than to Levaquin's older brother, ofloxacin (Floxin), also manufactured and distributed by Defendants.

23. Both Floxin and Levaquin were created and developed by Daiichi, Japanese Company who holds the patent on both agents. Daiichi assigned the patents to Defendants and gave Defendants an exclusive license to manufacture and market both its fluoroquinolone compounds to Aventis for manufacture and market in European counties. To date, Levaquin remains one of Daiichi's best selling pharmaceuticals.

24. Daiichi ensured that the post market surveillance of levofloxacin would be world-wide by creating an international database to keep track of adverse events. This database ensured that Defendants could not ignore the post market experience of levofloxacin in other countries.

25. Ofloxacin was first introduced into the Japanese market in September 1985. Defendants introduced ofloxacin, under the brand name of Floxin, in the United States six years later, in 1991.

26. Even before ofloxacin was marketed in Japan, Daiichi began researching products that could be the successor of ofloxacin. Daiichi wanted to develop a newer fluoroquinolone in order to be more competitive with Cipro and the other fluoroquinolones by developing a drug with the same or better characteristics of ofloxacin that could be used both orally and by injection.

27. After many derivatives of ofloxacin were explored and synthesized, Daiichi isolated what is now known as levofloxacin. Levofloxacin is a purified version of one optically active form of ofloxacin, more specifically the L-isomer.

28. Accordingly, ofloxacin and Levaquin are pharmacologically very similar, in fact, so similar that Defendants alleged in their New Drug Application for Levaquin that he safety profile of Levaquin would be expected to mirror that of ofloxacin.

29. Unfortunately, while Levaquin did closely follow the safety profile of ofloxacin, Levaquin was worse with respect to certain adverse effects, including tendon toxicity.

30. Defendants made no attempts to educate physicians in the United States about this unusual adverse event. Although Dear Doctors had been widely disseminated throughout Europe advising of Levaquin's tendon toxicity and the vulnerability of this adverse event to the elderly, Defendants did not so advise the U.S. physicians.

31. Defendants plan was to hide behind the class warning and blame any tendon injuries reported on the general pharmacological properties of fluoroquinolone antibiotic rather than on the L-isomer of the ofloxacin compound as the Aventis studies suggested.

32. Promotional material designed and distributed by Defendants, and more specifically by Ortho-McNeil, consistently omits the risk of tendon injury and other adverse effects on materials left with physicians.

33. Accordingly, physicians continued to prescribe Levaquin believing it to have the

same safety profile as Cipro and unaware of the heightened affect of Levaquin on the elderly population.

34. The Defendants, upon information and belief, have or may have failed to comply with all federal standards and requirements applicable to the sale of their prescription drug – Levaquin, including, but not limited to, one or more of the following violations:

a. The Defendants' prescription drugs are adulterated pursuant to 21 U.S.C. § 351 because, among other things, they fail to meet established performance standards, and/or the methods, facilities, or controls used for their manufacture, packing, storage or installation are not in conformity with federal requirements. See, 21 U.S.C. §351.

b. The Defendants' prescription drugs are adulterated pursuant to 21 U.S.C. § 351 because, among other things, their strength differs from or their quality or purity falls below the standard set forth in the official compendium for the drugs and such deviation is not plainly stated on their labels.

c. The Defendants' prescription drugs are misbranded pursuant to 21 U.S.C. §352 because, among other things, their labeling is false or misleading.

d. The Defendants' prescription drugs are misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. The Defendants' prescription drugs are misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use in those pathological conditions or by children where their use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f. The Defendants' prescription drugs are misbranded pursuant to 21 U.S.C. §352 because they are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. The Defendants' prescription drugs do not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which they are intended, including conditions, purposes, or uses for which they are prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which they are intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application.

h. The Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i. The Defendants' prescription drugs are misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j. The Defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drugs including degree and rate of absorption, pathways of biotransformation, percentage of dosage as unchanged drug and metabolites, rate or half-time of elimination, concentration in body fluids associated with therapeutic and/or toxic effects, degree of binding to plasma proteins, and/or the degree of update by a particular organ.

k. The Defendants violated 21 CFR § 201.57 because evidence was only available to support the safety and effectiveness of the drugs in selected subgroups of the larger

population with a disease, syndrome, or symptom and the labeling failed to describe the available evidence and state the limitations of usefulness of the drugs.

l. The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drugs.

m. The Defendants violated 21 CFR § 201.57 because the safety considerations regarding the prescription drugs are such that the drugs should be reserved for certain situations, and the Defendants failed to state such information.

n. The Defendants' prescription drugs are mislabeled pursuant to 21 CFR § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

o. The Defendants' prescription drugs are mislabeled pursuant to 21 CFR § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

p. The Defendants violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drugs and other drugs in the same pharmacologically active and chemically related class.

q. The Defendants' prescription drugs are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

r. The Defendants' prescription drugs violate 21 CFR § 210.1 because the process by which they are manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that they meet the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.

s. The Defendants' prescription drugs violate 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

t. The Defendants' prescription drugs violate 21 CFR § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

u. The Defendants' prescription drugs violate 21 CFR § 211.165 in that the prescription drugs fail to meet established standards or specifications and any other relevant quality control criteria.

v. The Defendants' prescription drugs violate 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drugs were not followed.

w. The Defendants' prescription drugs violate 21 CFR § 310.303 in that the prescription drugs are not safe and effective for their intended use.

x. The Defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are

or may be grounds for suspending or withdrawing approval of the application to the FDA.

y. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drugs as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drug experience.

z. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drugs, and evaluating the cause of the adverse event.

aa. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

bb. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

cc. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report followup."

dd. The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drugs or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well

as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

ee. The Defendants violated 21 CFR § 314.80 by failing to report adverse drug experiences at quarterly intervals for three (3) years from the date of approval of the application, and then at annual intervals.

ff. The Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

gg. The Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY
DEFECTIVE MANUFACTURING

35. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

36. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, designing, distributing, selling, and/or supplying of Levaquin.

37. Defendants designed, manufactured, marketed, and sold Levaquin to medical professionals and their patients, knowing that it would be ingested for the treatment of

infections.

38. The Levaquin manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce by Defendants was defective in its manufacture and construction when it left the hands of Defendants.

39. Levaquin as designed, manufactured, marketed and sold by Defendants reached Elga Ida Hindin without substantial change in its condition and was used by Elga Ida Hindin in a reasonably foreseeable and intended manner.

40. Levaquin was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Elga Ida Hindin, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Elga Ida Hindin have reason to believe that Levaquin was in a condition not suitable for her proper and intended use.

41. Levaquin was used in the manner for which it was intended, that is, for treatment of bacterial infections, which this use resulted in injury and death to Elga Ida Hindin.

42. Elga Ida Hindin was not able to discover, nor could she have discovered through the exercise of reasonable care, the defective nature of Levaquin. Further, in no way could Palintiffs have known that Defendants had designed, developed, and manufactured Levaquin in such a way as to increase the risk of harm or injury to the recipients of Levaquin.

43. Levaquin is defective in manufacture because of its propensity to cause tendon ruptures, serious tendon injuries, clostridia difficile infection and renal failure.

44. Levaquin is unreasonably dangerous because it was sold to Elga Ida Hindin without adequate warnings regarding, *inter alia*, the propensity of Levaquin to cause serious tendon injuries; the post-marketing experience with Levaquin; the increased risk of tendon

injury in patients over the age of 60; the numbers of tendon-related adverse events reported; and the probability of suffering an acute tendon injury when ingesting corticosteroids concomitantly with Levaquin or post Levaquin use.

45. Defendants failed to develop, manufacture, and make available alternative products were designed and/or manufactured in a safe or safer manner, even though such products were feasible and marketable at the time Defendants sold Levaquin to Elga Ida Hindin.

46. Defendants had knowledge and information confirming the defective and dangerous nature of Levaquin. Despite this knowledge and information, Defendants failed to adequately and sufficiently warn Elga Ida Hindin and her physicians that Levaquin causes serious tendon injuries and other effects including, without limitation, tendon ruptures, clostridium difficile infection and renal failure.

47. As a direct and proximate result of Defendants' wrongful conduct and failure to comply with federal standards and requirements, including the defective and dangerous nature, design and manufacture of Levaquin and the inadequate warnings, Elga Ida Hindin sustained injuries and was ultimately caused to die. Plaintiffs were caused to lose the loss, enjoyment and companionship of their mother and seek recovery of all damages allowed by law.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY DESIGN DEFECT

48. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

49. Defendants were the manufacturers, designers, sellers, distributors, suppliers, marketers, and/or those who placed in the stream of commerce Levaquin.

50. The Levaquin manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce by Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation. This design made the product unreasonably dangerous when reasonably safer, alternative designs existed.

51. The foreseeable risks associated with the design or formulation Levaquin, include, but are not limited to, the fact that the design or formulation of Levaquin, is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

52. As a direct and proximate result of Defendants' wrongful conduct and failure to comply with federal standards and requirements, including the defective and dangerous nature, design and manufacture of Levaquin and the inadequate warnings, Elga Ida Hindin sustained injuries and was ultimately caused to die. Plaintiffs were caused to lose the loss, enjoyment and companionship of their mother and seek recovery of all damages allowed by law.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY DEFECT DUE TO INADEQUATE WARNING AND INADEQUATE POST-MARKET WARNING/ MARKETING DEFECT

53. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

54. Defendants were the manufacturers, designers, sellers, distributors, suppliers, marketers, and/or those who placed in the stream of commerce the antibiotic, Levaquin.

55. The Levaquin manufactured, designed, sold, distributed, supplied, marketed,

and/or placed in the stream of commerce by Defendants was defective due to inadequate warning or instruction because Defendants knew, or should have known, that Levaquin causes serious tendon injuries, including, without limitation, tendon ruptures, clostridia difficile infection and renal failure and they failed to adequately warn consumers and/or their health care providers of such risks.

56. The Levaquin manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew, or should have known, that Levaquin causes serious tendon injuries, including, without limitation, tendon ruptures, clostridia difficile infection and renal failure and that Defendants failed to provide an adequate warning to consumers and/or their healthcare providers of the risk of serious bodily harm.

57. As a direct and proximate result of Defendants' wrongful conduct and failure to comply with federal standards and requirements, including the defective and dangerous nature, design and manufacture of Levaquin and the inadequate warnings, Elga Ida Hindin sustained injuries and was ultimately caused to die. Plaintiffs were caused to lose the loss, enjoyment and companionship of their mother and seek recovery of all damages allowed by law.

58. On information and belief, Defendants withheld and/or misrepresented to the United States Food and Drug Administration ("FDA") required information that was material and relevant to the performance of Defendants' product and Plaintiff's injuries are causally connected to this action.

FOURTH CAUSE OF ACTION
NEGLIGENCE

59. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

60. Defendants had a duty to exercise reasonable care in the manufacture, design, sale, distribution, supply, marketing, and/or placement of Levaquin into the stream of commerce, including a duty to ensure that Levaquin, did not pose a significantly increased risk of bodily harm and adverse events.

61. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Levaquin into interstate commerce in that Defendants knew, or should have known, that Levaquin, caused such significant bodily harm and was not safe for ingestion by consumers.

62. Defendants also failed to exercise ordinary care in the labeling of Levaquin, and failed to issue to consumers and/or their healthcare providers adequate warnings of the risk of serious bodily injury by the ingestion of Levaquin.

63. Despite the fact that Defendants knew, or should have known, that Levaquin posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Levaquin as a safe fluoroquinolone antibiotic.

64. The Defendants knew, or should have known, that consumers, such as Elga Ida Hindin, would foreseeably suffer injury as a result of the Defendants' and/or their corporate predecessors' failure to exercise ordinary care as described above.

65. As a direct and proximate result of Defendants' wrongful conduct, negligence and failure to comply with federal standards and requirements, including the defective and dangerous nature, design and manufacture of Levaquin and the inadequate warnings, Elga Ida Hindin sustained injuries and was ultimately caused to die. Plaintiffs were caused to lose the

loss, enjoyment and companionship of their mother and seek recovery of all damages allowed by law.

FIFTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

66. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

67. Defendants and/or their corporate predecessors expressly warranted that Levaquin was a safe and effective antibiotic.

68. The Levaquin manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to consumers when ingested in routinely administered dosages.

69. As a direct and proximate result of the Defendants' breach of warranty, as well as the Defendants' failure to comply with federal standards and requirements, Elga Ida Hindin sustained injuries and was ultimately caused to die. Plaintiffs were caused to lose the loss, enjoyment and companionship of their mother and seek recovery of all damages allowed by law.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

70. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

71. At the time Defendants manufactured, marketed, sold, and distributed Levaquin, Defendants knew of the use for which Levaquin was intended and impliedly warranted Levaquin to be of merchantable quality, fitness and safe for such use.

72. Elga Ida Hindin and her healthcare providers reasonably relied upon the skill

and judgment of the Defendants as to whether Levaquin was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters.

73. Contrary to the implied warranty, Levaquin was not of merchantable quality or safe for its intended use because it was unreasonably dangerous as described herein.

74. As a direct and proximate result of the Defendants' breach of warranty, as well as the Defendants' failure to comply with federal standards and requirements, Elga Ida Hindin sustained injuries and was ultimately caused to die. Plaintiffs were caused to lose the loss, enjoyment and companionship of their mother and seek recovery of all damages allowed by law.

SEVENTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

75. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

76. The Defendants had actual knowledge based upon studies, published reports and clinical experience that Levaquin created an unreasonable risk of serious bodily injury to consumers, or should have known such information.

77. The Defendants intentionally or negligently omitted this information in their product labeling, promotions and marketing and instead labeled, promoted and marketed their products as safe in order to avoid losses and sustain profits in their sales to consumers.

78. Elga Ida Hindin and her physicians reasonably relied to her detriment upon Defendants' actions and omissions in their labeling, marketing, and promotions concerning the serious risks posed by the products. Elga Ida Hindin reasonably relied upon Defendants' representations to her and/or her healthcare providers that Levaquin was safe for human

consumption and/or use and that the Defendants' labeling, marketing and promotions fully described all known risks of the products.

79. As a direct and proximate result of the Defendants' negligent actions and omissions, as well as the Defendants' failure to comply with federal standards and requirements, Elga Ida Hindin sustained injuries and was ultimately caused to die. Plaintiffs were caused to lose the loss, enjoyment and companionship of their mother and seek recovery of all damages allowed by law.

EIGHTH CAUSE OF ACTION
FRAUD

80. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

81. Upon information, Plaintiffs believe that Defendants, through their officers, directors, sales agents, marketing agents, representatives, and employees, intentionally, willfully, and knowingly, fraudulently misrepresented to the medical community, the FDA, and U.S. consumers, including Elga Ida Hindin and her healthcare providers that Levaquin had been adequately tested in clinical trials and was found to be safe and effective as an antibiotic.

82. Defendants knew, and should have known, at the time they made their fraudulent misrepresentations, that their misrepresentations were false and fraudulent regarding the dangers and risk of adverse health events associated with use of their antibiotic. Defendants made their fraudulent misrepresentations willfully, wantonly, and with recklessly disregarded and depraved indifference for the safety and well being of the users of their antibiotic, such as Elga Ida Hindin.

83. Defendants' fraudulent misrepresentations were made knowingly, intentionally, and with the intent of defrauding and deceiving the medical community, Plaintiff, and the

public, and also inducing the medical community, Plaintiff, and the public, to recommend, prescribe, dispense, and purchase Defendants' fluoroquinolone antibiotic.

84. Defendants' fraudulent misrepresentations intentionally concealed the following material information:

a. Defendants' fluoroquinolone based antibiotic was not as safe and effective as other antibiotics;

b. Ingestion of Defendants' flouroquinolone based antibiotic would not result in a safe and more effective method than other antibiotic;

c. The risks of harm associated with the use of Defendants' flouroquinolone based antibiotic was greater than the risk of harm associated with other antibiotic;

d. The risk of adverse events with Defendants' antibiotic were not adequately tested in patients, but Defendants knowingly failed to adequately test the drugs, knew that the risks of harm associated with the use of Defendants' antibiotic was greater than the risks of harm associated with other forms of antibiotics, yet knowingly made material misrepresentations and omissions of fact regarding the testing date on which Elga Ida Hindin relied in ingesting Defendants' antibiotic, Levaquin;

e. Defendants intentionally and knowingly failed to disclose and intentionally concealed the adverse events discovered in the clinical studies, and intentionally concealed and fraudulently misrepresented clinical trial results;

f. Defendants were aware and had knowledge of the dangers involved with the use of Defendants' flouroquinolone antibiotic, Levaquin, which dangers were greater than those associated with other antibiotics;

g. Defendants' Levaquin was defective and caused dangerous and adverse side effects, including, but not limited to the specific injuries specifically described elsewhere in this Complaint;

h. Defendants' flouroquinolone antibiotic was negligently and defectively manufactured;

i. Defendants' flouroquinolone antibiotic was negligently and defectively designed;

j. Defendants were under a duty to disclose to Elga Ida Hindin and her physicians, the defective design and formulation of Defendants' fluoroquinolone antibiotic, which design and formulation heightened the risk of suffering the injuries specifically describes in this Complaint and suffered by Plaintiff.

85. Defendants had sole access to material facts concerning the defective nature of their products and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who ingest Levaquin.

86. Defendants' intentional concealment and omissions of material facts concerning the safety of Defendants' antibiotic was made negligently, knowingly, unlawfully, purposefully, willfully, wantonly, fraudulently, and with reckless disregard for the health and safety of Plaintiff, with reckless intent to mislead, to cause Plaintiff's physicians and healthcare

providers to purchase, prescribe, and/or dispense Defendants' fluoroquinolone based antibiotic; and to mislead Elga Ida Hindin into reliance upon Defendants' fraudulent misrepresentations and use of Defendants' fluoroquinolone based antibiotic for treatment as a safe and effective antibiotic.

87. At the time Defendants made their misrepresentations, and at the time Elga Ida Hindin used Defendants' fluoroquinolone based antibiotic, Elga Ida Hindin was unaware of the Defendants' falsehoods and reasonably believed them to be true.

88. Defendants knew, and had reason to know, that Defendants' fluoroquinolone based antibiotic could and would cause serious personal injury to the users of Defendants' fluoroquinolone based antibiotic and that the product was unreasonably and inherently dangerous in a manner that exceeded any purported inaccurate warnings given by Defendants.

89. In reliance upon Defendants' false and fraudulent misrepresentations, Elga Ida Hindin was induced to, and did use Defendants' fluoroquinolone antibiotic thereby sustaining severe and permanent personal injuries and damages. Defendants knew, and had reason to know, that Elga Ida Hindin and her physicians and other healthcare providers did not have the ability to determine the true facts intentionally concealed by Defendants in prescribing and ingesting Defendants' fluoroquinolone antibiotic and would not have, respectively, prescribed and ingested Defendants' fluoroquinolone antibiotic, if the true facts regarding Defendants' fluoroquinolone antibiotic had not been concealed by Defendants.

90. Plaintiffs reasonably relied upon Defendants' misrepresentations where knowledge of the concealed facts was critical to understanding the true dangers inherent in the use of Defendants' fluoroquinolone antibiotic.

91. As a result of Defendants' failed research and insufficient testing, Defendants

negligently, knowingly, willfully, wrongfully, and intentionally distributed false information, including, but not limited to, representing to and assuring Plaintiff, the public, and Plaintiff's healthcare providers and physicians, that Defendants' fluoroquinolone antibiotic was safe for use as a fluoroquinolone antibiotic. As a result of Defendants' research and testing, Defendants intentionally omitted, concealed, and suppressed from the medical community, Plaintiff, and other consumers the true results of Defendants' clinical tests and research.

92. Defendants had a duty when disseminating information to the public to provide truthful information and a parallel duty not to deceive the public, Plaintiff, her healthcare providers, and the FDA.

93. The information distributed by Defendants to the public, the medical community, the FDA, and Elga Ida Hindin was in the form of reports, press releases, advertising campaigns, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of Defendants' fluoroquinolone antibiotic

94. Defendants intentionally made material misrepresentations to the medical community and the consuming public, including Plaintiff, regarding the safety of Defendants' fluoroquinolone antibiotic, specifically that Defendants' fluoroquinolone antibiotic did not have dangerous and/or serious adverse health effects and safety concerns, in particular when administered to patients with renal insufficiency. Defendants intentionally made material representations to Plaintiff, the public, and the medical community regarding the safety of Defendants' fluoroquinolone antibiotic, specifically that Defendants' fluoroquinolone antibiotic was as safe as other fluoroquinolone antibiotics.

95. Defendants' intent and purpose in making these misrepresentations was; to

deceive and defraud the public, the medical community, and Plaintiff; to gain the confidence of the public, the medical community, and Plaintiff; to falsely assure them of the quality of Defendants' fluoroquinolone antibiotic and their fitness for use; and to induce Plaintiff, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use Defendants' fluoroquinolone antibiotic.

96. Defendants made claims and representations in their documents submitted to the FDA and their reports to the public and to healthcare professionals that Defendants' fluoroquinolone antibiotic did not present serious health risks.

97. Defendants' misrepresentations were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and egregiously without regard to the true facts.

98. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of Defendants' fluoroquinolone antibiotic to the public at large, and Elga Ida Hindin in particular, for the purpose of influencing the sales of products known by Defendants to be dangerous and defective, and not as safe and effective as alternative fluoroquinolone antibiotic.

99. Defendants' wrongful conduct constitutes fraud and deceit and was committed and perpetrated willfully, wantonly, and purposefully.

100. As a foreseeable, direct, and proximate result of Defendants' described acts and omissions, Elga Ida Hindin was caused to suffer the serious and dangerous side effects as are more specifically described in this Complaint.

101. As a direct and proximate result of Defendants' acts and omissions and Plaintiff's ingestion of Defendants' defective product, Elga Ida Hindin sustained injuries and

was ultimately caused to die. Plaintiffs were caused to lose the loss, enjoyment and companionship of their mother and seek recovery of all damages allowed by law.

JURY DEMAND

Plaintiffs demand a trial to a jury as provided by law.

DEMAND FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

a. For damages associated with the wrongful death of Elga Ida Hindin;

b. For damages associated with the loss, enjoyment and companionship of Elga Ida Hindin;

c. Attorneys' fees, expenses, and costs of this action;

d. Prejudgment interest; and

e. Such further relief as this Court deems necessary, just, and proper.

Respectfully submitted this 11th day of June, 2008.

McNULTY LAW FIRM

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Pro Hac Vice Applications to be filed